EXHIBIT 58

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Cephalon, Inc
c/o CIMA Labs
41 Moores Road
Frazer, PA 19355

Attention: Carol S. Marchione
Senior Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your New Drug Application (NDA) dated August 31, 2005, received August 31, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FENTORA (fentanyl buccal tablet), 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg.

We acknowledge receipt of your submissions dated September 9, January 5, 6, 20, February 22, 24, March 2, 13, 24, 29, April 7 (2), 24, May 11, 23, 26 (2), June 2, 5, 16 (2), 21, 23, 26 (2), 27, 29 (2), July 25 and September 7, 12, 18, and 19, 2006.

The July 25, 2006, submission constituted a complete response to our June 29, 2006 action letter.

This new drug application provides for the use of FENTORA for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, Medication Guide and the components of your Risk Minimization Action Plan (RiskMAP). Marketing of this drug product and related activities are to be in accordance with the substance and procedures of all FDA regulations.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the Medication Guide, immediate container [blister] and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Your FENTORA RiskMAP is an important part of the post marketing risk management for fentanyl buccal tablet. The primary goals of your RiskMAP are to minimize the use of FENTORA by opioid nontolerant individuals, minimize misuse of FENTORA, and minimize unintended (accidental) exposure to FENTORA.

Your RiskMAP must include the following components:

1. Implementation of a program and distribution of materials to educate prescribers, pharmacies, nurses, and patients about the risks and benefits of FENTORA.

2. Implementation of a reporting and data collection system for safety surveillance.

3. Implementation of a plan to monitor, evaluate, and determine the incidence of use of FENTORA by opioid nontolerant individuals, misuse of FENTORA, and unintended (accidental) exposure to FENTORA.

The FENTORA RiskMAP submitted on August 31, 2005 and finalized in your submission dated September 19, 2006, and as described in the attached document, adequately addresses each of these requirements. This plan includes ongoing assessment and periodic reporting to FDA of the operation of the program and needed revisions, if any. Any change to the program must be discussed with FDA prior to its institution and is subject to FDA's determination that the required components are still present. We expect your continued cooperation to resolve any problems regarding the FENTORA RiskMAP that may be identified following approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-947**." Approval of this submission by FDA is not required before the labeling is used.

The proprietary name for this product and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages 0 to 17 years until June 28, 2011.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain in pediatric patients ages 0 to 17 years.

   Final Report Submission: September 25, 2011

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

Under 21 CFR Part 208, we have determined that this product poses a serious and significant public health concern requiring the distribution of a Medication Guide. Fentanyl buccal tablet is a product for which patient labeling could help prevent serious adverse effects and inform the patient of serious risks relative to benefit that could affect their decisions to use, or continue to use, the product. Therefore, a Medication Guide is necessary for safe and effective use of this product and FDA hereby approves the enclosed Medication Guide submitted on July 25, 2006. Please note that:

1. This Medication Guide must be reprinted at the end of the package insert (21 CFR 201.57(f)(2));

2. You are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product (21 CFR 208);

3. The final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

4. You are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided (e.g., affixed on the container, provided with the product, etc.).

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Amendable Road
Beltsville, MD 20705-1266

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please submit one market package (that does not contain any active drug) of the drug product when it is available.

We acknowledge your amendment dated June 27, 2006, that you will the change the tablet color of all strengths to white before marketing and that the manufacturing process for all strengths will be the same as that which is currently used for the 200-mcg tablets.

We acknowledge that you will provide three months of accelerated and long-term stability data for at least one lot of each strength within six months from the date of NDA approval.

We acknowledge, based on your submission dated June 26, 2006, that you will to reduce the specification for (b)(4) impurity in active drug substance from (b)(4) to NMT (b)(4) by the end of December 2006 and update this in your first NDA Annual Report.

Your product is approved with a shelf-life of 24 months.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

Package Insert
Medication Guide
Blister and Carton Labels
Summary of RiskMAP

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport
9/25/2006 05:28:02 PM